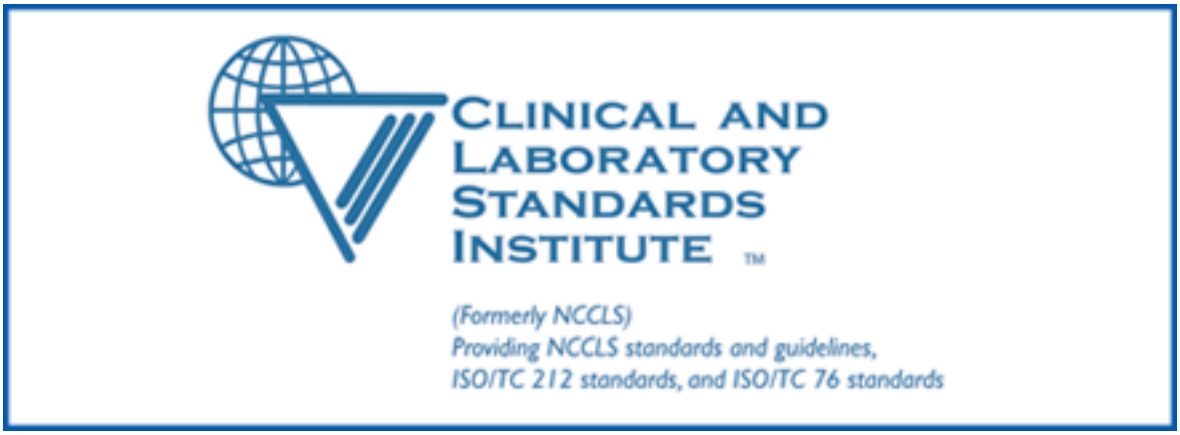
LIS9-A
Vol. 23 No. 15
Formerly ASTM E2118-00

Standard Guide for Coordination of Clinical Laboratory Services within the Electronic Health Record Environment and Networked Architectures



This document covers the process of defining and documenting the capabilities, the logical data sources and pathways of data exchange within a given network architecture of a Health Information Network (HIN) serving a set of constituents.

NCCLS

NCCLS...

Serving the World's Medical Science Community Through Voluntary Consensus

NCCLS is an international, interdisciplinary, nonprofit, standards-developing, and educational organization that promotes the development and use of voluntary consensus standards and guidelines within the healthcare community. It is recognized worldwide for the application of its unique consensus process in the development of standards and guidelines for patient testing and related healthcare issues. NCCLS is based on the principle that consensus is an effective and cost-effective way to improve patient testing and healthcare services.

In addition to developing and promoting the use of voluntary consensus standards and guidelines, NCCLS provides an open and unbiased forum to address critical issues affecting the quality of patient testing and health care.

PUBLICATIONS

An NCCLS document is published as a standard, guideline, or committee report.

Standard A document developed through the consensus process that clearly identifies specific, essential requirements for materials, methods, or practices for use in an unmodified form. A standard may, in addition, contain discretionary elements, which are clearly identified.

Guideline A document developed through the consensus process describing criteria for a general operating practice, procedure, or material for voluntary use. A guideline may be used as written or modified by the user to fit specific needs.

Report A document that has not been subjected to consensus review and is released by the Board of Directors.

CONSENSUS PROCESS

The NCCLS voluntary consensus process is a protocol establishing formal criteria for:

- the authorization of a project
- the development and open review of documents
- the revision of documents in response to comments by users
- the acceptance of a document as a consensus standard or guideline.

Most NCCLS documents are subject to two levels of consensus—"proposed" and "approved." Depending on the need for field evaluation or data collection, documents may also be made available for review at an intermediate (i.e., "tentative") consensus level.

Proposed An NCCLS consensus document undergoes the first stage of review by the healthcare community as a proposed standard or guideline. The document should receive a wide and thorough technical review, including an overall review of its scope, approach, and utility, and a line-by-line review of its technical and editorial content.

Tentative A tentative standard or guideline is made available for review and comment only when a recommended method has a well-defined need for a field evaluation or when a recommended protocol requires that specific data be collected. It should be reviewed to ensure its utility.

Approved An approved standard or guideline has achieved consensus within the healthcare community. It should be reviewed to assess the utility of the final document, to ensure attainment of consensus (i.e., that comments on earlier versions have been satisfactorily addressed), and to identify the need for additional consensus documents.

NCCLS standards and guidelines represent a consensus opinion on good practices and reflect the substantial agreement by materially affected, competent, and interested parties obtained by following NCCLS's established consensus procedures. Provisions in NCCLS standards and guidelines may be more or less stringent than applicable regulations. Consequently, conformance to this voluntary consensus document does not relieve the user of responsibility for compliance with applicable regulations.

COMMENTS

The comments of users are essential to the consensus process. Anyone may submit a comment, and all comments are addressed, according to the consensus process, by the NCCLS committee that wrote the document. All comments, including those that result in a change to the document when published at the next consensus level and those that do not result in a change, are responded to by the committee in an appendix to the document. Readers are strongly encouraged to comment in any form and at any time on any NCCLS document. Address comments to the NCCLS Executive Offices, 940 West Valley Road, Suite 1400, Wayne, PA 19087, USA.

VOLUNTEER PARTICIPATION

Healthcare professionals in all specialties are urged to volunteer for participation in NCCLS projects. Please contact the NCCLS Executive Offices for additional information on committee participation.

Preface

In 2001, ASTM Committee E31 decided to restructure its operations, with the intent of focusing on standards-development issues such as security, privacy, and the electronic health record. Part of the reorganization plan was to explore the option of transferring responsibility for nine E31.13 standards to NCCLS.

The NCCLS Area Committee on Automation and Informatics, at its meeting in April 2002, reached a positive assessment of the value of the ASTM standards and encouraged the NCCLS Executive Offices staff to pursue negotiations with ASTM on transferring these standards to NCCLS.

Following this transfer, these nine standards (formerly ASTM E792; E1029; E1238; E1246; E1381; E1394; E1466; E1639; and E2118) have been redesignated as NCCLS standards LIS1 through LIS9.

The Area Committee on Automation and Informatics has assumed responsibility for maintaining the documents and will revise or update each document in accord with NCCLS Administrative Procedures.

This document is the equivalent of ASTM E2118-00 but has been redesignated and is now maintained by NCCLS. This document has been approved as an American National Standard (ANSI/ASTM E2118-00).

Suggested Citation

(NCCLS. *Standard Guide for Coordination of Clinical Laboratory Services within the Electronic Health Record Environment and Networked Architectures.* LIS9-A [ISBN 1-56238-497-X]. NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2003.)

Published
April 2003

ISBN 1-56238-497-X
ISSN 0273-3099

Standard Guide for
Coordination of Clinical Laboratory Services within the Electronic Health Record Environment and Networked Architectures

1. Scope

1.1 This guide covers the process of defining and documenting the capabilities, the logical data sources and pathways of data exchange within a given network architecture of a Health Information Network (HIN) serving a set of constituents. It is not a technical implementation standard but, rather, it describes how the implementation methods and techniques can be used to logically coordinate clinical laboratory services and Electronic Health Record (EHR) systems involving participating organizations and sites connected by a networked communication system. It covers the content of the nodes and arcs of the resulting logical network involving both laboratory and EHR-capable sites. It also considers the various purposes and organizational arrangements for coordinating laboratory services within the network boundaries and the considerations for connections among external networks.

1.2 It refers to other standards for conventions within various data domains, such as Clinical Laboratory Information Management Systems (CLIMS) and EHR systems, and for messaging conventions. It is intended to outline how integration of CLIMS and EHR Systems can be undertaken to result in a transparent clinical decision support environment, regardless of the underlying implementation architecture, by describing the logical interoperability of information domains as facilitated by Information and Communications Technology (ICT).

1.3 It is directed at clinical laboratorians, information system managers and information systems vendors for use in planning and implementing coordinated laboratory services through effective dialogue.

2. Referenced Documents

2.1 *ASTM Standards:*

E 1239 Guide for Description of Reservation/Registration-Admission, Discharge, Transfer (R-ADT) Systems for Electronic Health Record (EHR) Systems[1]
E 1340 Guide for Rapid Prototyping of Computerized Systems[1]
E 1384 Guide for Content and Structure of the Electronic Health Record (EHR)[1]
E 1467 Specification for Transferring Digital Neurophysiologic Data Between Independent Computer Systems[1]
E 1578 Guide for Laboratory Information Management Systems (LIMS)[2]
E 1633 Specification for Coded Values Used in the Electronic Health Record[1]
E 1712 Specification for Representing Clinical Laboratory Procedure and Analyte Names[1]
E 1713 Specification for Transferring Digital Waveform Data Between Independent Computer Systems[1]
E 1714 Guide for Properties of a Universal Healthcare Identifier (UHID)[1]
E 1715 Practice for an Object-Oriented Model for Registration, Admitting, Discharge and Transfer (RADT) Functions in Computer-based Patient Record Systems[1]
E 1744 Guide for View of Emergency Medical Care in the Computer-based Patient Record[1]
E 1762 Guide for Electronic Authentication of Healthcare Information[1]
E 1769 Guide for Properties of Electronic Health Records and Record Systems[1]
E 1869 Guide for Confidentiality, Privacy, Access and Data Security Principles for Health Information Including Computer Based Patient Records[1]
E 1985 Guide for User Authentication and Authorization[1]
E 1986 Guide for Information Access Privileges to Health Information[1]
E 1987 Guide for Individual Rights Regarding Health Information[1]
E 1988 Guide for Training Persons Who Have Access to Health Information[1]
E 2017 Guide for Amendments to Health Information[1]
E 2084 Specification for Authentication of Healthcare Information Using Digital Signatures[1]
E 2085 Guide on Security Framework for Healthcare Information[1]
E 2086 Guide for Internet and Intranet Healthcare Security[1]
PS 115 Specification for Audit and Disclosure Logs for Use in Healthcare Information Systems[1]

2.2 *ANSI/IEEE Standards:*[3]

ANSI X3.172 American National Dictionary for Information Systems
ANSI/IEEE 610.2 Standard Glossary of Computer Applications Terminology
ANSI/IEEE 610.5 Standard Glossary of Information Management Terminology

[1] *Annual Book of ASTM Standards*, Vol 14.01.
[2] *Annual Book of ASTM Standards*, Vol 03.05.
[3] Available from IEEE, 445 Hoes Lane, P.O. Box 1331, Piscataway, NJ 08855-1331.

ANSI/IEEE 610.12 Standard Glossary of Software Engineering Terminology
ANSI/IEEE 729 Fundamental Terms in Software Engineering
ANSI/IEEE 830 Software Requirements Specification
ANSI/IEEE 1074 Standard for Developing Software Life Cycle Processes
ANSI/IEEE 1074.1 Guide for Implementing Life Cycle Processes
ANSI/IEEE 1058 Software Project Management Plans
ANSI/IEEE 1062 Recommended Practice for Software Requirements
ANSI/IEEE 1063 Software User Documentation
ANSI/IEEE 1073 Framework and Overview
ANSI/IEEE 1073.2 Application Profile Framework and Overview
ANSI/IEEE 1073.3.1 Transport Profile
ANSI/IEEE 1073.4.1 Physical Layer-Cable Connected
ANSI/IEEE 1074 Standard for Developing Life Cycle Processes
ANSI/IEEE 1074.1 Guide for Developing Life Cycle Processes
ANSI/IEEE 1220 Standard for Application and Management of the System Engineering Process
ANSI/IEEE 1233 Guide to Preparing System Requirements Specifications
ANSI/IEEE 1320.1 Standard for Conceptual Modeling Language - Syntax and Semantics for IDEF0
ANSI/IEEE 1320.2 Standard for Conceptual Modeling Language - Syntax and Semantics for IDEF1X97 (IDEF Object)
ANSI/IEEE 1362 Guide for Information Technology - System Definition -Concept of Operations Document
ANSI/IEEE 1490 Guide to Project Management Body of Knowledge
ANSI/IEEE 1498 Trial Use Standard for Information Technology - Software LifeCycle Processes - Software Development: Acquirer - Supplier Agreement
ANSI/IEEE 12207.0 Standard for Information technology - Software Life Cycle Processes
ANSI/IEEE 12207.1 Guide for Information technology - Software Life Cycle Processes - Life Cycle Data
ANSI/IEEE 12207.2 Guide for Information technology - Software Life Cycle Processes - Implementation Considerations
IEEE P1157.1 Trial Use Standard for Healthcare Data Interchange - Information Model Methods

2.3 *ANSI/HL7 Standards:*[4]

ANSI/HL7 Interface Standard v2.3.1
HL7 Message Development Framework v 3.0 Jan 1997

2.4 *ISO Standards:*[5]

ISI/IEC TR 9789 Information Technology - Guidelines for the Organization and Representation of Data Elements for Data Interchange - Coding Methods and Principles
ISO 12200 Computer Applications in Terminology - Machine-Readable Terminology Interchange Format (MARTIF) - Negotiated Interchange
ISO 12620 Computer Applications in Terminology - Data Categories
ISO IS 12207 Information Technology-Software Life Cycle Processes
ISO IS 15188 Project Management Guidelines for Terminology Standardization
ISO WD 15288 System Life Cycle Processes
ISO 15440 Guide for Life Cycle Processes
ISO 15189 Quality Management in the Clinical Laboratory
ISO DIS 15194 Measurement of Quantities in Samples of Biologic Origin - Reference Materials
ISO DIS 15193 Measurement of Quantities in Samples of Biologic Origin - Reference Methods
ISO 15195 Requirements for Reference Measurement Laboratories
ISO 15711 Traceability of Calibration and Control Materials

2.5 *Other Standards:*

ANSI/ADA 1000.0 Introduction, Model Architecture, and Specification Framework[6]
ANSI/ADA 1000.1 Individual Identification[6]
ANSI/ADA 1000.2 Codes and Nomenclature[6]
ANSI/ADA 1000.3 Individual Characteristics[6]
ANSI/ADA 1000.4 Population Characteristics[6]
ANSI/ADA 1000.5 Organization[6]
ANSI/ADA 1000.6 Location[6]
ANSI/ADA 1000.7 Communication[6]

[4]Health Level 7, 3300 Washtenaw Ave., Suite 227, Ann Arbor, MI 48108.
[5]Available from International Standards Organization, 1 Rue de Varembe, Case Postale 56, Crt1221, Geneva 20 Switzerland.
[6]Available from the American Dental Association (ADA), Dept. of Dental Informatics, 211 East Chicago Ave., Chicago, IL 60611.

ANSI/ADA 1000.8 Healthcare Event[6]
ANSI/ADA 1000.9 Health Material[6]
ANSI/ADA 1000.10 Health Services[6]
ANSI/ADA 1000.11 Health Service Resources[6]
ANSI/ADA 1000.12 Population Health Facts[6]
ANSI/ADA 1000.13 Patient Health Facts[6]
ANSI/ADA 1000.14 Health Condition Diagnosis[6]
ANSI/ADA 1000.15 Health Service Plan[6]
ANSI/ADA 1000.16 Patient Health Service[6]
ANSI/ADA 1000.17 Clinical Investigation[6]
ANSI/ADA 1000.18 Comments Subject Area[6]
DICOM Supplement 15 Visible Light Image, Anatomic Frame of Reference, Accession and Specimen for Endoscopy, Microscopy, and Photography[7]
CEN ENV 1613 Medical Informatics - Messages for the exchange of laboratory information[8]
CEN ENV 1614 Healthcare informatics - Structure for nomenclature, classification and coding of properties in clinical laboratory sciences[8]
CEN ENV 12017 Medical Informatics Vocabulary (MIVoc)[8]
CEN ENV 12264 Categorical Structures of Systems of Concepts -Model for Representation of Semantics (MOSE)[8]
Internet RFC 1521 N. Borenstein, N Freed MIME [Multipurpose Internet Mail Extensions] Purpose: Mechanisms for Specifying and Designating the Format of Internet Message Bodies, Bellcore Innosoft, Sept. 1993, ANSI X12[8]
NCCLS AUTO1-A Laboratory Automation: Specimen Container/Specimen Carrier[9]
NCCLS AUTO2-A Laboratory Automation: Bar codes for Specimen Container Indentification[9]
NCCLS AUTO3-A Laboratory Automation: Communications with Automated Clinical Laboratory Systems, Instruments, Devices and Information Systems[9]
NCCLS AUTO4-A Laboratory Automation: Systems Operational Requirements, Characteristics and Information Elements[9]
NCCLS AUTO5-A Laboratory Automation: Electromechanical Interfaces[9]
ANSI/NCCLS ASTP2 Point of Care In-vitro Diagnostic Testing[9]
ANSI/NCCLS GP19 Laboratory Instruments and Data Management Systems: Design of Software User Interfaces and Software Systems Validation, Operations and Maintenance[9]
IUPAC/IFCC Silver Book: Compendium of Terminology and Nomenclature of Properties in Clinical Laboratory Sciences[10]
IUPAC/IFCC Properties and Units in Clinical Laboratory Sciences X Properties and Units in General Clinical Chemistry[10]
IUPAC/IFCC Properties and Units in Clinical Laboratory Sciences XII Properties and Units in Clinical Pharmacology and Toxicology[10]

3. Terminology

3.1 *Definitions:*

3.1.1 Terminology related to general information systems appears in X3.172, IEEE 610 series, and IEEE-729 Terminology relating generally to healthcare information appears in CEN EN 12264 and EN 12017, and in UMLS. The terms used frequently from these sources appear here, in addition to those terms specific to this guide.

3.1.2 *health information network*—a set of data domains (nodes) and communications pathways (arcs) serving a healthcare constituency with information management services.

3.1.3 *identifier*—a symbol used to name, indicate or locate. Identifiers may be associated with such things as data structures, data items, or program locations. (IEEE 610.12)

3.1.4 *practitioner, licensed*—an individual at any level of professional specialization who requires a public license/certification to practice the delivery of care to patients. A practitioner may also be a provider. (E 1384)

3.1.5 *provider*—a business entity which furnishes healthcare to a consumer. It includes a professionally licensed practitioner who is authorized to operate a healthcare delivery facility. (E 1384)

3.2 *Acronyms*—The following acronyms are used in this standard and may also appear in other referenced documents:

[7]Available from ACR/NEMA.
[8]Available from CEN, Central Secretariat, Rue Strassart 36, B-650, Brussels, Belgium.
[9]Available from NCCLS, 940 West Valley Rd, Suite 1400, Wayne, PA 19087-1898.
[10]Available from IUPAC, c/o CRC Press, 2000 Corporate Blvd. NW, Boca Raton, FL 33431.

CAP	College of American Pathologists
CDC	Centers for Disease Control and Prevention, Dept. of Health and Human Services
CDSS	Clinical Decision Support Systems
CLIMS	Clinical Laboratory Information Management System
CPR	Computer-based Patient Record
DHHS	Department of Health and Human Services
EC	Electronic Commerce
EDI	Electronic Data Interchange
HIN	Health Information Network
IDS	Integrated Delivery Systems
ISA	Information Systems Architecture
LAS	Laboratory Automation System
LIMS	Laboratory Information Management System
MDSS	Management Decision Support System
MCO	Managed Care Organization
MPI	Master Person/Patient Index
NCVHS	National Committee on Vital and Health Statistics
NPF	National Provider File
NPI	National Provider Identifier
NPS	National Provider System
POC	Point-of-Care
POCT	Point-of-Care Testing
PPO	Preferred Provider Organization
SSAN	Social Security Account Number (also SSN)
UMLS	Unified Medical Language System

4. Significance and Use

4.1 Health Information Networks (HINs) have arisen in recent years as a way to share common information within organizational arrangements among healthcare facilities which have been formed into large, more comprehensive Integrated Delivery Systems (IDS) and Managed Care Organizations (MCO) offering a full range of healthcare services, both inpatient and ambulatory. The specific organizational structures to which the term was originally applied most probably have evolved into something quite different. Furthermore, IDS organizations are contracting with other IDSs by offering specialty services, such as clinical laboratory services, that have a market larger than a single IDS itself and buying such services for themselves rather than offering them internally. Because of the proliferation of specialty laboratory procedures and the introduction of automation of laboratory operations which require a larger volume to begin offering than is internally available, specialty laboratory procedures are being marketed beyond just the host IDS. Moreover, initiatives directed at automation in the clinical laboratory will need a frame of reference for the global information to which that automation will contribute.

4.2 Another aspect is the development of instrumentation for testing at Point-of-Care (POCT) for high value immediate-benefit services. POCT, however, needs supervision and training from skilled laboratorians, whether that supervision comes from within the IDS or outside of it. This range of operation is only achievable by distributed HIN structures which must have the same quality of clinical and data services as offered by laboratories close at hand. Data Management of POCT has been documented separately but such data management must be placed into the broader context of this guide. Thus, this guide should be used to first organize the global domain and then the interconnected subdomains.

4.3 In order to provide common systematics for documenting coordination of laboratory services within the HIN structure, the problem has been broken down within this guide into identification and characterization of, first, the global domain and the business framework into which coordinated laboratory services will fit as a component. Then the constituent subdomains are addressed and are represented as nodes in the network. Next, the characterization of the arcs in the network are treated, again focusing on the logical content and not the implementation. When the logical structure of the network is well understood in terms of its scope, purpose and constituents, then enumeration of alternative implementation strategies and methods/techniques can be effectively considered, followed by selection of an alternative, or a set of compatible alternatives. Finally, selection of an evaluation methodology and its use in managing ongoing operation and evolution of lab services coordination as part of the overall evolution of the HIN itself are covered. Such an approach should then allow laboratorians, information system personnel, and any external suppliers who may be involved, to define, plan, implement, and utilize a networked architecture for coordination of the lab service component of an EHR environment implemented in a networked architecture. This development can be organized into the Life Cycle Processes defined in IS 12207 and 15288 and in ANSI IEEE 12207.0, 12207.1, 12207.2. CLIMS used to serve as components within this architecture can be procured with the help of LIS3.

5. Identification of the Network Domain

5.1 In order to encompass all of the aspects to be served by a networked architecture provided for coordinating the services requested of the clinical laboratory by each specific care setting and type, the global business objectives must be stated and the increasingly specific content of the domain to be networked must be established. This is usually done using a matrix model that defines all of the dimensions starting from the most general to the more technical. Table 1 gives an example of such a matrix. The technique, detailed further in 5.2, has been described by Zachman **(1)**[11] as the Information Systems Architecture (ISA) Framework and has been implemented using several software tools **(2–4)**. From examination of this matrix format, further modeling of the business components, the processes and the data structures and representations is sequentially undertaken in order to identify the nodes and arcs of the network that support the business case for the network. The detailed modeling of the data domains, using the business considerations given in 5.2, is then applied, as appropriate, to each node. This activity will identify both the data that is required for activities internal to the node and that which may be exchanged with other domains. The business case for each node must be understood as part of the identification of the node and so a detailed internal business model should result that drives the process model for that node and which may be independent of the models for a different node of the same type. Since the interactions of the nodes are known from identification of the arcs, those data needed by each arc can be generally identified and later characterized, as noted in Section 7. Following these steps, which identify the requirements of a network, effective delineation of implementation strategies that are consistent with the business case can be documented and a selection made of implementation tools and techniques that are appropriate to the selected Life Cycle.

5.2 *Modeling of the Business Domain*—A Zachman ISA Framework matrix of the dimensions of the informatics standards applied to healthcare is given in Table 1. From this broad domain, standards dealing with those aspects relevant to coordination of laboratory services are shown in Table 2. The enterprise that is developing a networked architecture for coordinating laboratory services in an EHR environment must refine this perspective to that embracing the interests of the enterprise. This refinement will begin by looking at each of the cells in the upper left of the matrix dealing with Scope and Concept of Operations - See IEEE 1362 (ISA matrix cells 1-6) and then moving to the right followed by moving down from content issues to implementation issues reflecting use of a particular technology and techniques. Once a refined framework is available, then more specific modeling of Processes and Data take place. These will be focused first on the source and destination information domains (nodes) and then on the arcs.

5.2.1 *Representative Case*—Most healthcare enterprises, and probably most laboratory services (Table 3), will consist of both ambulatory and inpatient settings (6.3) in addition to central laboratory sites appropriately located. The "Concept of Operations" (ANSI/IEEE 1362) prepared as Cells 1-2 and 1-3 in Table 1 should enumerate, for the enterprise, the range of support that each laboratory location will provide with respect to the identified care settings served. The focus of Cell 1-6 in Table 1 should be to document the specimen and patient referral patterns of the care sites (see Appendix X1, Fig. X1.1) and to show the enterprise organizational network diagram. The pattern of intercommunication between nodes, the logical network, would be prepared as Cell 3-6. An example of this is shown in Appendix X1, Fig. X1.2. These boundary conditions allow each laboratory node to identify its own business plan for internal management purposes as a complement to the Enterprise Business Plan. The example in Appendix X1 gives a basic documentation of this process phase for a laboratory serving a family practice ambulatory care clinic and a general practice hospital. POC Testing laboratories are present in the Family Practice Ambulatory Clinic. The initial ISA Matrix is shown in Table 2 which identifies the models for the enterprise and those for each POCT location needed to characterize the main information domains. Process models for the enterprise and each location are developed followed by data models for CLIMS and EHR domains as guided respectively by 6.2 and 6.3. These models identify data elements and associated value sets required throughout the enterprise. When full characterization of nodes has been completed, additional node specific data will next be identified.

5.3 *Modeling of the Processes*—Several techniques are available for the modeling of processes, including IDEF0 (Ref **(3)** and IEEE 1320.1), Use Cases **(4)** and Data Flow Diagrams **(6)**. In each technique both actions and the "actors" **(4)**, or individuals/organizations, must be identified and their activity described first globally and then in detail in order to identify scenarios involving clinical laboratory services. An example of this technique is shown below. Process models are generally hierarchical if using IDEF0 (but also using Use Cases), starting first at the global level and then increasingly refined to an appropriate level of detail needed to fully understand the activities within the defined domain. The purpose of these process models is to systematically and comprehensively examine all of the processes producing information that affects the defined business case noted in 5.2. They should be applied first to the Enterprise and then to the nodal domains. Fig. 1 shows a representative Use-case/Actors model for a POL type POCT scenario and setting (see 6.2) in an enterprise view.

[11] The boldface numbers in parentheses refer to the list of references at the end of this standard.

5.4 *Modeling of the Data Domains*—Data modeling, as noted in 5.2, involves systematically and comprehensively describing the DATA involved in processes detailed in 5.3. It includes identifying or constructing the terminologies needed to populate value sets for the defined data attributes. For example, this technology function must draw on consensus vocabularies developed by professional specialty groups, public agencies or other involved organizations with broad involvement in healthcare, if true interoperability is to be achieved (See Specification E 1712 and the LOINC.[12] The value sets may be selected from these more global vocabularies. In order to truly understand the data structures and data representations, an understanding of the processes is required. Thus, processes modeling should, but many times due to haste does not, precede data modeling. In the case where data modeling shuns formal process modeling, an intuitive - and thus generally incomplete - process model drives the data modeling. The urge to omit the process modeling phase should be resisted. Rather, the modeling activities may be carried out iteratively first at a high level and then at increasing detail. LIS8 and Practice E 1715 delve into data modeling in constituent functional domains. These activities, however, need to be placed in the context established by the Business model (5.2) and the Process models (5.3). This task is taken up in Section 6.

6. Characterization of the Network Nodes

6.1 One of the reasons that this standard is a guide and not a specification is that it is not possible to detail, in a global document such as this, the specifics of the various factors which may need to be considered at the individual enterprise level. Likewise, for each of the node types only a general guide to the issues that need to be considered is given here. The steps given in IS 12207 on Software Life Cycles and 15288 on System Life Cycles will need amplification and specification as part of the documentation for a specific enterprise and specific project. In considering the types of nodes that may be involved in coordination of clinical laboratory services, a wide variety of activities become recognized that may not generally be included as separate data domains. Some of those included are shown in Table 4. Because the view of clinical laboratory services from the perspective of the performers of the services in each of these other domains may not be a realistic picture of the activity required to conduct its role at these other nodes, this section sets out to identify, and generally characterize, the business, the processes, and the data that may be involved in a representative real instance of each type of node in a working network so that network planners and designers have a comprehensive reference to these characteristics. While a real instance may contain one or more of these functions, but not necessarily all of those outlined here, it will allow planners/designers to identify the existing processes at that node and the data needed to support them. Thus, the informaticians, the laboratorians, the practitioners, the operators and the administrative staff can clearly document the functional and data components that are truly required for quality performance of their role in their organization.

6.2 *CLIMS Domains (Including Point-of-Care)*—CLIMS nodes in an enterprise network may be of a variety of types, as shown in Table 3. Each node may have its own size and configuration of CLIMS to interface with instrumentation and process, in a hierarchical fashion, the data relevant to its own operations. Each may have a somewhat different process and data model depending upon the homogeneity of the organization of which it is a part, or the function which it provides to the organization. These models should be identified within the business model.

6.2.1 *Office Practice Laboratory*—The office practice laboratory has generally been oriented to CLIA-88 "waived" tests performed by non-laboratorians. Nevertheless, these results must find their way expeditiously into the EHR (or paper records) serving the practice and laboratory records supporting quality control of such testing. (see example in Fig. 1) This is a special case of POCT which is dealt with elsewhere. In group practices which may be served by another clinical laboratory with trained laboratory staff and having a range of general laboratory measurements that support a general patient population, a separate CLIMS configured from the requirements in LIS8 may serve the information management requirements of the group practice and interface with the EHR domains serving the group. Since the EHR configuration of each group may not be identical for all members, the nodes which are different must be separately described and clearly documented. If a group uses a common configuration accessed by each member then a common description will suffice.

6.2.2 *Large Clinic Laboratory*—A clinical laboratory serving a large clinic offers a much larger range of services and this requires much more extensive capabilities and a detailed configuration of its CLIMS. Either the CLIMS itself, or at least some of the EHR nodes served, may require interoperability with a LIMS serving environmental or pharmaceutical support settings. Such may be the case if patients served have possible environmentally induced health conditions; in Guide E 1384, Segment 7 of the EHR has a repository for data documenting exposure to environmental stressors whereas Segment 11 documents diagnostic testing measurements which may characterize the biologic response to such exposure. The coordination of both stressor exposure and diagnostic measurements may be carried out as part of the requested clinical laboratory services. LIS8 develops the CLIMS requirements for handling this responsibility. If such environmental stressor measurement services to a large clinic are not handled by the associated clinical laboratory, the procedures and required data needed by the

[12] See the website, http://www.regenstrief.org.

EHR nodes must be carefully documented, particularly if the clinical laboratory handling the requested measurements will be involved in correlating the environmental exposure measurements made separately to the measurements made in the clinical laboratory.

6.2.2.1 The CLIMS in such a setting will take on a structured clinical decision support capability and be responsible for organizing the data in the most effective way for decision support of the practitioner clients of the clinic. The CLIMS capability must enumerate and document the sources of its knowledge, its representation and its mode of use in supporting clinical decisions of its practitioners. In a networked architecture, referential data in other nodes may be utilized but the process and the data nodes must support the business model (see 5.2) of the clinic and its laboratory with respect to how this is done.

6.2.3 *Hospital/Inpatient Facility Laboratory*—Hospital inpatient facility laboratory enterprises will undoubtedly service many patient care nodes within the organization's architecture. Consequently, the business case (see 5.2) and the informatics standards (see 5.2, 5.3) must be identified that are associated with each of the patient care nodes served in order to define the CLIMS requirements for supporting these care sites and for those sites served outside the administrative boundaries of the enterprise. Forums must also be arranged to depict the homogeneity or diversity of the sites served, their situation and the possibility of agreeing on common conventions needed at each level of the ISA framework for each of these patient care site nodes in the laboratory network.

6.2.4 *General Reference Laboratory*—General reference laboratories are separate enterprises serving many nodes which represent a wide variety of care settings. Each of these enterprises must model its enterprise setting based upon its business case but its Domain Information Model (DIM) must have commonality with that of its customers in order for the arcs of information flow to function optimally. Thus a common model is an advantage that both customers and suppliers must understand in designing an Information architecture to meet its business needs. As common conventions (standards) for Domain Information Models are agreed upon, these should form a starting point for documenting the enterprise Information Architecture for the general reference clinical laboratory.

6.2.5 *Non-clinical Domains*—Nonclinical domains include clinical and health services research databases, for example, registries, clinical trial databases, etc. Examples of non-clinical information domains which will draw on clinical laboratory data and procedures are listed in Table 5.

6.2.6 *Point-of-Care Workstations*—Point-of-Care workstations constitute a special situation beyond that described in 6.2.1 concerning Office Practice Laboratories above (see example in Fig. 1). This node must be carefully characterized in terms of the "Clinical View" served by the workstation and its broader role in the entire architecture. Examples of this kind of node include workstations in Emergency Departments (see Guide E 1744) and in critical care settings. Others might include Anesthesiology or Operating Suite settings where major segments of the EHR may be needed to support the clinical view, in addition to any attached measuring instrumentation. A careful characterization of contributions of the clinical laboratory or pharmaceutical care information domains needs to be made. These nodes carefully manage all contributed data in an integrated fashion to support the clinical decision setting and situation, leaving the attributes utilized stored in the nodes and information domains contributing to the clinical view. How this is done needs careful documentation of the business, the processes and the data supporting the setting and the situation.

6.2.7 *MPI Functions in Clinical Laboratories*—An MPI capability would allow the laboratory to process specimens from any contractual arrangement that the host enterprise might make. Likewise, it would allow transparent send-out of specimens by the clinical laboratory to specialty laboratories for infrequently conducted procedures. The facility identifier from the National Provider File of HCFA would track such send outs. Every clinical laboratory will need to uniquely identify the patients whose specimens are submitted to it for measurements. Certain demographic data may be needed in order to interpret measurements made. In spite of this, only key individuals may need to know the individual patient and access these data. Privacy and confidentiality will be key in a networked architecture for the EHR Environment. Guides E 1869, 1785-1788 and E 2085 delve into the responsibilities of clinical laboratories and its supporting CLIMS to meet these requirements which are mandated in PL 104-191 (HIPAA). This responsibility will not diminish in the Automated Clinical Laboratory. The unique identification of patients associated with submitted specimens in the extended environment of the IDS will be conducted by the MPI function documented in Guide E 1239 to acquire for the CLIMS (see LIS8) that demographic data needed for providing its services to the practitioner. Either HL7 messages or CORBA Services (see 7.3.4) can provide the messaging/data transfer capability for both the MPI and the mediated MPI used and also for the R-ADT functions needed to provide this capability. Each CLIMS site will need to clearly document the way that this component of the networked architecture will be integrated into the CLIMS/EHR domains and how the privacy/confidentiality aspects are unequivocally dealt with.

6.2.8 *The National Provider File and the Clinical Laboratory*—The NPF is being created to first serve HCFA for Medicare patients. It has the capability of characterizing every provider, that is, every individual and organization involved in healthcare. It contains a Taxonomy of Providers which can categorize each entity to which an NPI is assigned. It will have the ability to be accessed, with appropriate security control, via telecommunications. Thus, it complements the MPI by being able to validate the identity of "Providers" and provide, under controlled

conditions, certain attributes associated with that identity. It will be a resource for the CLIMS and EHR environments (see 6.3.2) to populate and keep up to date those attributes needed regularly in information management within the CLIMS domain. The way that it will evolve after its introduction in January 2002 remains to be seen. Nevertheless, planning a networked architecture to take advantage of the potential capabilities should be envisioned. Administrative services messages, as described in 7.3.4, will be the primary vehicle for implementation of the services of this node. Consult LIS8 in planning use of data from this node.

6.3 *EHR Domains*:

6.3.1 At the current time there are few fully functional EHR Systems and all have arisen from proprietary perspectives without the frame of reference of a Common Domain Information Model (CDIM) with which the system should be conformant. Moreover, many systems are merely unique databases to capture data produced for claims processing or data reporting that stem from historically unique situations. The terms "Data Warehouses" or "Data Repositories" are used for many systems rather than the rather specific definition of a EHR as one that conforms in structure and representation to Guide E 1384. The process and data models of the existing systems at each node must be documented and compared with the data and processes required at the other nodes with which each must communicate, as identified in the global network. This should be done using Guide E 1384 and Specification E 1633 as reference, in addition to any working documentation of the embryonic CDIM. The specific clinical views, such as that for EMS defined in Guide E 1744, should be identified in order to understand the clinical decisions being made at that node (see HL7). The EHR nodes must be sufficiently broken down hierarchically in the family of models for the node in order that cost effective implementation alternatives can subsequently be identified. For the laboratory, the nature of the requesting dialog and the decision support capabilities for interpreting returned results must be identified, if those nodes are to be transparently integrated regardless of the location of the performing laboratory.

6.3.1.1 The following subcategories that focus on particular settings and "Clinical Views" should be considered:

National Provider File
Master Patient Indexes
EMS pre-hospital
EMS Receiving Hospital: Initial Care
EMS Receiving Hospital: Trauma Hospital
Inpatient Care-General Service
Inpatient Care-Specialty Service
Ambulatory Care Facility-Family Practice
Ambulatory Care-Specialty Practice
Ambulatory Care-Public Health Practice

6.3.1.2 Each of these categories needs to be considered from the point of view of integration of laboratory services into the decision support dialog for practitioners in concert with the defined CLIMS nodes. Some of these considerations will be dealt with in the following sections.

6.3.2 *National Provider File*—The National Provider File (NPF) is a component of the National Provider System (NPS) which catalogs all practitioners and provider organizations who submit claims for Medicare and is administered by the Health Care Financing Administration (HCFA) of the US Department of Health and Human Services (DHHS). Each practitioner and provider organization have unique identifiers which are intended to be part of the standards involved in healthcare as developed by the ANSI Health Informatics Standards Board (HISB). As part of that standards program, HCFA agreed to develop the NPI as part of their responsibilities in administering Medicare since it had a requirement to identify individual practitioner and organizations which could then become a central resource for that function in throughout healthcare as the need evolved. Organizations and individuals will need to be identified within the structure and content of the EHR, as documented in Guide E 1384, and also in networked architectures nodes that will need this function for which the NPS will be the reference source. Proper authority will be required to query this file and to extract required information for the enterprise domain and this capability must be recognized in the design of the network domain. HCFA will be responsible for maintaining the currency of NPF and will contract to various SDOs for its components. The Data Interchange Standards Association[13] will maintain the Taxonomy of Providers. Clinical Laboratories, among other provider organizations that are identified with the NPI for each node, can be used in messaging traffic as well for operations within each node.

6.3.3 *Master Patient Index and the EHR*—A number of organizations are now considering online MPIs which would allow online identification of patients and key attributes. Such a capability would allow CLIMS (see 6.2.7) to identify specimens sent either from outside the host facility or from other enterprise domains accessible from the MPI, depending upon how it is established, and to return results to the EHR. The characteristics of the MPI domain is described in Guide E 1239 but the use of MPI capabilities for the clinical laboratory is detailed in both the CLIMS Requirements (LIS8) and in the documentation of the network architecture. That architecture documentation must

[13]See the DISA website, http://www.wpc-edi.com/taxonomy/codes.html.

include its logical role of the MPI in both the EHR and CLIMS domains as well as its implementation aspects which are discussed in Sections 8 and 9.

6.3.4 *EMS Pre-Hospital*—Each EMS Mobil Unit is an identifiable and characterized node in a networked architecture. To the extent that the identified EMS unit conducts requests for laboratory services, its purposes and supporting data structure should be documented and, from that documentation, the needed arcs should be documented which characterize the data exchange requirements to and from that Mobil EMS unit and from other nodes in the EMS system. While the component functions of an EMS Mobil Unit may be similar nationwide, each EMS system has its own requirements and these need documentation as part of the definition and implementation process. For example, specimens such as emergency runs for blood typing and blood product delivery to the intended receiving node, require documentation in order to foster evolution of appropriate capabilities.

6.3.5 *EMS Receiving Hospital: Initial Care*—Depending upon the enterprise and role assigned to the facility in the EMS system, laboratory services may be requested which are required but which may not be completed before the patient is stabilized and sent on to a designated EMS Trauma hospital. Even if the patient remains at the initial receiving facility, the measurements requested of the laboratory need to be judiciously joined with the EHR. This may be the case if the services are POC in the Emergency Department (see Guide E 1744), but the data flow for these situations needs to clearly be documented in order to understand the information requirements of the node.

6.3.6 *EMS Receiving Hospital: Trauma Hospital*—Depending upon the structure of the regional trauma system, the EMS Trauma Hospital needs a Domain Information Model that shows how it can receive information about clinical laboratory services that have originated at the scene or in an initial receiving facility regardless of whether the results of these services may have been already reported at those nodes. Blood services is one example of such data when a specimen is drawn at the scene and taken to a regional blood center for typing and cross-match prior to dispatching blood products to the receiving facility. Due to exigencies and distance, these destinations may change during transport but the information needed is common at the receiving nodes and the data flow arcs in the regional system. Both data structures and data representation (vocabularies) are components of the DIM for this node.

6.3.7 *Inpatient Care-General Service*—In inpatient care, general laboratory services involve a wide range of attributes for Clinical Orders developed in Guide E 1384. The linkage of the attributes to messaging attributes is given in LIS5 and HL7 v2.3.1. The way that these attributes are used in the "business" of the enterprise must be defined in the Concept of Operations Document (IEEE 1362). The way that clinical decision support functions occur in the Clinical Order Process must be part of the Concept of Operations and Requirement Specifications for the architecture components. The way that the structure of the Information Architecture supports the general information services in the Enterprise inpatient setting must also be part of the Concept of Operations and reflected in the Requirements. This general service posture will then be the basis for stating Specialty Practice information requirements as noted in 6.3.8.

6.3.8 *Inpatient Care-Specialty Practice*—Using the general information services requirements in 6.3.7, the Clinical Views of the supporting clinical decisions occurring in the Specialty Practice must be carefully constructed so that they draw on the general attributes from the Clinical Order (Segment 10, Guide E 1384) used in requesting services from the clinical laboratory. These Specialty Practice Views must have consistency of content in order for the observations/measurements recorded to optimally support the sequence of steps in an intervention or treatment plan. For example, lab services used in Views supporting a trauma setting must be organized to show observations consistent with those used in the general surgery occurring in subsequent stabilizing, reconstructive and rehabilitative care such that the trajectory of patient status can be clearly seen.

6.3.9 *Ambulatory Care-Family Practice*—Family practice is probably the most fundamental care setting in healthcare but each practice has a different profile of information needs and access requirement for patient records. As clinical laboratory services are considered for each practice node in an Enterprise, a brief Concept of Operations document should be prepared depicting that practice node's relationship to the broader Enterprise environment. Physician's Office Lab (POL) nodes of POC Testing need to be identified so that later models of the needed data can relate the practice lab data to the data flow arcs and the EHR/CLIMS data models for the practice setting. These steps will lead, in the Requirements Specification for the Project to the (implementation) technology-independent data structures and representations needed by the practice. These Requirements then allow selection of alternative implementing technologies and can organize each step (see Section 8) in acquiring functional components for the practice enterprise architecture. Key functional components that will be part of any practice are: Registration/Admitting/Discharge and Transfer (R-ADT), Master Patient Index (MPI), Health Condition Problem List, Clinical Order Entry, Encounter Recording, Treatment Plan and these are developed in Guides E 1239 and E 1384.

6.3.10 *Ambulatory Care Specialty Practice*—Specialty Practice Information Architectures build upon the fundamental capabilities noted for Family Practice in 6.3.9 but also must relate to those inpatient aspects discussed in 6.3.8. The special decision support capabilities and modules supporting specialty data gathering for diagnostic procedures and observations will require component functional modules that condition patient record and referential context independent data from a variety of in-practice and external data sources. The usage of these data

conditioning procedures and referential data (for example, Practice Guidelines and other knowledge bases: see Table 1 and Cells 4-1 and 5-1) all need description in the Requirements Specification, if they are expected to interoperate with data from the EHR. Requirements to access patient data from other nodes (such as resident care facilities) in order to follow patient response to treatment in different settings, will be needed particularly if the practitioner will be relying on laboratory specialists to aid in interpretation of observation/measurements made by the laboratory. Thus, the Concept of Operations and Requirements documents will be more extensive than is the case in Family Practice settings.

6.3.11 *Ambulatory Care Public Health Practice*—Public Health Practice settings deal with a wide range of constituents, many of whom may not have an established family practitioner. Even in the best situations, the public health setting may deal with emergency, trauma or infectious disease situations and could use access to the basic demographic data already gathered by the family practitioner. Even in immunization activities, the need for clinical lab services to validate immune status may be needed and the results will need communication to the regular practitioner to ensure follow up. Thus, again the basic Concept of Operations and Requirements documents are required in order to clearly understand the information services and Requirements for functional modules. Such documentation then allows the public health agency to plan the evolution of its architecture as its services change in the context of the Community Health Information Network Architecture. Thus, when new clinical services are offered, a project can be quickly organized to acquire just the needed information services from suppliers in the market.

6.4 *Public/Private Reporting Agency Domains*:

6.4.1 the advent of networked architectures has elicited a recognition of the fact that reportable data needed for policy, research or resource management can be derived from either the EHR or the CLIMS nodes, depending upon satisfaction of defined criteria. The nature of the receiving node in a reporting system, and its privacy/confidentiality requirements, must be documented as well as the process and data models that derive from its business model. These business models must be obtained from each participating organization in the reporting network in order to proceed with modeling their uses. Either the process or the data models may be supplied by those organizations insofar as they characterize the nature of the arcs emanating from that node since these will be required by the nodes with whom they communicate, if the arc is to be optimally functional. Some of these agencies are shown in Table 6.

6.4.2 A variety of purposes attend reportable data that is aggregated by the receiving agencies into research, resource management or policy databases and which may be used to form “Registries” or other statistical or analytical database structures. Some of these are shown in Table 7.

6.5 *Referential Information Domains*—Both laboratory and clinical practice draw on data published in the scientific literature. The amount of this data has become so immense that any one individual cannot carry it around in his/her head but, rather, needs it quickly in the context of clinical decision-making and during dialog supporting daily work actions. A networked architecture provides the capability for centralized collection of such referential data with subsequent distributed access to these data in an appropriate fashion. For coordination of laboratory services internally, the data items used by the laboratory will be largely different from the items needed by the practitioner. Nevertheless, there is a common body of referential knowledge base data needed by both the laboratory and the practitioner in guiding the requests for laboratory services and utilization of the resulting observations/measurements. Some of these data are listed in Table 8. Common conventions (standards) for the elements of these structures are critical to interoperability and are only just now being considered. Many reference data are terminologic and these classes are shown in Table 9.

6.5.1 *Terminologies*—A terminology is a collection of terms in a specialty area. Names of measurement procedures and metrology related to the clinical laboratory (see IUPAC/IFCC) will need to be compatible throughout an enterprise domain. Specification E 1712 describes how to construct names to be used in these collections but a clear understanding of how they should be used in the EHR for documenting care and for decision support processes, possibly involving knowledge bases (see 6.5.3), will need to be clearly defined and documented so that both the information domains and messaging use them in a consistent fashion. The LOINC Terminology **(10)**, now part of the NLM UMLS vocabulary, uses the rules stated in the Specification E 1712. Training of practitioners in terminologies will be involved. Terminologies may need to be developed for special aspects of either the EHR or the CLIMS Information domains. If so, IS 15188 should be used to conduct such projects.

6.5.2 *Test Directories*—Probably the most important reference data structure in a clinical laboratory is that containing the measurement procedures performed and the analytes associated with that procedure. Paragraph 6.5.1 discusses the terminologies for the names of the procedures and analytes but the Laboratory Test Directory (see LIS8) will have a structure that reflects the simplicity or complexity of the enterprise's needs. Payer's needs for “Medical Necessity” attributes involves a set of associated attributes that details the health conditions/diagnoses for which the procedure provides information supporting clinical decisions. Cost, price, and other resource attributes are also indicated. Each preferred name may have associated one or more local or short names and one or more codes from defined coding schemes that classify the procedure or measurement in various ways (see ISO/IEC TR 9789). The business case developed in 5.2 will help identify the attributes and standards relevant to the construction of a

data model for this data structure.

6.5.3 *Knowledge Representations*—Each enterprise must identify the context-independent knowledge structures needed to support its business case. One such structure now commonly mentioned is "Practice Guidelines." Though few common conventions and collected data by these conventions currently exist, consensus efforts toward this end are underway, with directed interest by the FDA. These data structures provide organization of the concepts that depict their meaning to the practice of healthcare. For the clinical laboratory, they provide a means of guiding the request function for integrating services that is consistent with best current understanding and recommended practices. To function in a CLIMS, they must be keyed with the specific patient data in order to return the implications of that knowledge base for that individual. The analysis of the Business case in 5.2 is the initial step in identifying the requirements for such knowledge representations and the role that such structures will play in the enterprise's business.

6.5.4 *Laboratory Commercial Products*—A particular referential data structure for clinical laboratories is one containing attributes of products and services involved in operating the clinical laboratory. These attributes should support the business case developed in 5.2 and aid in the resource management functions related to the volume and type of services requested by customer nodes in the enterprise environment. They should be used to develop Electronic Commerce capabilities in supplying the clinical laboratory node by means of Electronic Data Interchange (EDI) capabilities according to the nature of the underlying platform and implementation strategy developed in Section 8. These attributes should aid in developing costs and pricing structures for service contracts involving nodes in the enterprise or among enterprises that may be customers of the particular enterprise offering services outside its immediate domain.

6.6 *Commercial/Administrative Domains*—As enterprise organizational structures evolve and healthcare financing arrangements change, the resource management sequelae of coordinated laboratory services must also change to correctly reflect the legal requirements for reimbursement for laboratory services. Clear, simplified, understandable data structures will be needed within defined subdomains in order to reflect the explicit criteria for payments. Likewise, logistical support of the clinical laboratory will require gathering of data related to the estimated consumption of supplies and maintenance of equipment, not to mention documentation of types, and modes of utilization of laboratory personnel, if effective cost accounting is to occur. Suppliers now utilize Electronic Commerce (EC) and Electronic Data Interchange (EDI) and these capabilities reflect the ability to deliver just-in-time, obviating large inventories to buffer changing logistical needs due to changing patterns of services. The CLIMS nodes will need to know how to use this capability internally as well as in messaging implementation (see 7.3.3) of the arcs connecting to supplier nodes.

6.7 *Pharmaceutic Services*—It is now clear that integration of professional services available within pharmacies with the patient care activities now documented in the EHR will shortly evolve in concert with the EHR evolution itself. The Pharmaceutic Care Information available from pharmacists must draw on the treatment plans and clinical medication orders written by practitioners and must emphasize compliance to those treatment plans and orders. Additionally, direct advice by pharmacists to practitioners during the decision process leading to clinical orders will also most likely be part of the process. This decision process will also involve the clinical laboratory when therapeutic drug monitoring may be involved. The nature of those interactions are described in a later standard.

6.8 *Imaging Services*—Imaging services for the clinical laboratory relate to the provision of image reports from anatomic pathology, hematology or microbiology examinations of patient specimens. These are best posted to the EHR for consideration by the practitioner in addition to the online copies stored in electronic form within the CLIMS domain. This could be in addition to archival physical material such as slides, residual specimens, etc. within the laboratory. Use of the DICOM standard for storage of electronic copies, as well as for a communication format, is recommended since this provides the associated attributes in addition to the bitmap. These attributes allow identification of the originating sites so that the image archives can be accessed for later retrieval of images, even if the laboratory itself may have been organizationally absorbed. Such capabilities must be part of the enterprise Domain Information Model developed from the Business Case in 5.2.

7. Characterization of the Network Arcs

7.1 Each information domain (node) captures, structures, stores and manages data within its boundaries but must create defined data constellations in order to communicate with other domains. "Messages" are logically and structurally defined data constellations packaged for interchange. These constellations constitute the Arcs of the network and are discussed here in order to elaborate a process for understanding what information needs to be exchanged, why the interchange is required, and what alternatives exist for how it should be handled. Modeling is introduced as a mechanism for structuring this understanding. This modeling complements its use within the source and destination data domains.

7.2 *Modeling for Definition of Arc Content*:

7.2.1 Modeling is being used within healthcare informatics not only for definition of messaging by HL7, X12N and DICOM SDOs in the United States but also by CEN TC 251 in Europe. Modeling is also being used within the ANSI HISB SDOs as part of its Standing Committee on Standards Development Coordination to coordinate the models being used for definition of messages with those being used for the source and destination data domains. ASTM, ADA and DICOM are primarily involved in domain modeling, although several ASTM messaging standards are closely coordinated with HL7. The primary modeling methodology used is Object-Oriented (See IEEE 1320.2 IDEF1X97-Objects) but the Entity-Relationship modeling conventions and tools are converging with those which are object-oriented through the work of the IEEE IDEF effort that originated in the Integrated Computer Aided Manufacturing (ICAM) efforts in the Department of Defense which began twenty five years ago. For this section, reference to the use of object-oriented modeling by HL7 will be used.

7.2.2 The Message Development Framework (MDF) **(8)**, now used by HL7, describes a process of sequentially developing four models: Use Case with Actors (Process Scenario) Model, Information Model, Interaction Model and General Message Design Model. The application of this process to messages is described in those standards and will not be detailed here but, rather, the compatibility of the process for messages with the use of these methods for characterizing source and destination domains will be considered in this document. For coordinating laboratory services, the role of the modeling techniques needs to be clearly defined within the structure of the Zachman Framework for the enterprise (see 5.2 and 5.3) so that the role of these steps is clearly understood in the global context. The Use Case Model is consistent with the process models produced by the IDEF0 modeling convention. The use of the technique is carefully limited by HL7 to the needs of message definition but if an activity as pervasive as laboratory services in healthcare is to be effectively coordinated, the Use Case/Process models must consistently reflect concepts over the global domains of the enterprise so that the definition of requirements for the enterprise, beginning with these models, must reflect this consistency in the scope defined at the outset.

7.2.3 The data needs for messaging within an enterprise, assuming it can be bounded, may be less than that identified generally for messaging standards. Nevertheless, for those elements in common, the definitions of the data elements (object attributes) must be identical, as must the value sets. Moreover, the definitions within the source and destination data domains constituting the nodes must be carefully harmonized even if, for the current time, data is not exchanged outside of the specific node because that requirement may rapidly change. Thus, the Actors and Use Cases must be carefully thought through for the long term, since the resulting requirements, and hierarchy of models, will proceed from the scenarios defined for these Uses and Actors.

7.2.4 *Modeling of the General Message Descriptions*—Both the CEN ENV 1613 and the HL7 Message Development Framework document describe a process for designing message syntax notations that serve a defined need. The process begins in these documents in defining Scenarios, (messaging) Domain Information Models, focused General Message Descriptions based on the Domain models and then Hierarchical (General) Message descriptions. Scenarios lead to Use Case (Process Models) and then Interaction Models with any associated State Transition Diagrams. These documents focus on the use of the processes for standard message development. But within the Life Cycle of systems contained in an Enterprise Architecture into which the particular components dealt with in a given project must fit, the Concepts of Operations that were described in Sections 5 and 6 must also be modeled and dealt with in a Life Cycle context. Thus, the Domain models used in this message development/selection process must draw on all of the source and destination domain related models and reflect the entire interoperation potential that will be reflected in a Requirements Specification tied to the Project Management Plan for the introduction of the component into the Enterprise Architecture. The use of common model notation and broad models obviates the need to start from scratch but rather draws on professional consensus of the meaning of broad common concepts that will be part of the Message Domain Information Model. The models also reflect the broad needs reflected in the Business Concept of Operations for the Enterprise. General Message Descriptions that are implementation independent set the stage for alternative Implementable Message Specifications discussed in 7.2.5.

7.2.5 *Modeling and the Implementable Message Specifications*—In a given Enterprise environment, different message syntaxes may be required for exchanging similar information with different information domains within the Enterprise Architecture but they may be based upon the same set of models. This part of the process translates the model into the generally sequential organization of the attributes needed for messaging or other forms of information interchange. It is at this point that existing standard message specification may be used as part of profiles of messages to achieve a particular purpose. The models allow understanding of the purpose and help identify where existing or new message specifications are needed in the context of the Enterprise architecture and how the semantics inherent in these models will achieve the Enterprise purpose. The HL7, CEN, IEEE MEDIX documents will be useful in selecting and documenting these alternatives within the Life Cycle Process context.

7.3 *Identification of Purposes and Trigger Events for Data Interchange*—One important aspect of characterizing network arcs, regardless of the level of decomposition, is to document the purpose (need for) exchange of data constellations between source and destination domains and to explicitly define the criteria for the "Trigger Event." Such "Trigger Events" support scenarios defined by Use Cases with actions in Process Models. Automated pointers

to referential objects and their associated context-insensitive attributes require only reference to the source data element at the context-sensitive level in whatever notation may be used in documenting the source and destination data domains. Certainly, as documented in 5.4 and Section 6, consistent conventions that have been used for these data domains should be used for exchangeable data constellations. It is conceivable, for instance, that the business/administrative data related to patient encounters documented in an EHR domain might be structured into separate subdomains from the clinical EHR domain during the design of the overall EHR node. Likewise, in a CLIMS domain patient-specific data may be separated from workstation domains where it may not be needed for managing specimen flow and workstation events. In some CLIMS environments existing within a patient care setting, as differentiated from a geographically separated reference laboratory environment, the patient attributes may reside in the EHR itself as a subdomain. In this situation, access to patient attributes needed for interpretation of observations may require a data interchange only of a narrowly defined data constellation from the EHR subdomain. This data constellation may be either the same or different in the case of a networked architecture that uses a reference laboratory for the data interpretation function. In different implemented networks, the logical constellations may be the same even though the implementation techniques may be totally different. Thus, it is important to clearly document the purposes for, and the criteria activating, an exchange via a defined arc separately from the implementation approaches dealt with in Section 8. Many of these ideas were described in 1977 **(7)**.

7.3.1 *Requests for Laboratory Services*—Arcs, which are Requests for Laboratory Services (Laboratory Clinical Orders), originate in a practitioner's source domain and terminate in a laboratory services information domain. In an IDS enterprise where a number of laboratory service domains serve a number of practitioner settings, the variants of these requests must be composed of the same data elements and data representations throughout the enterprise, if the information about the laboratory services is to be consistent and informative, regardless of the view or viewer. In 7.2.4, the content of the arcs must be carefully coordinated with the data content of the source and destination nodes and all nodes must consistently make use of the same concepts (data elements) in the same way. This will be particularly true for data elements which control trigger events in coordinating requests for laboratory services, since some data elements will have a contextual nature and some will involve context insensitive attributes associated with referential data which may be part of central reference domains (nodes) as described in 6.5 and further noted in 7.3.6. The data model for the enterprise must document these data relationships and how they are involved in the clinical decision support environment. LIS8 develops the information requirements for the CLIMS domain while Guide E 1384 and Specification E 1633 develop requirements for the EHR environment, particularly Clinical Orders; LIS5 and HL-7 v2.3 map how these data requirements are used in common within the source and destination data domains with their use in messaging.

7.3.2 *Reports of Requested Observations/Measurements*—Following internal laboratory processing of specimens associated with requested laboratory services (see LIS8), measured/observed values must be returned to the requester in a form enabling their display in a way best supporting clinical decision-making by the requesting practitioner. The display process may be a node quite independent of the CLIMS. Standard message constellations of data are therefore the mechanism of interchange. LIS2, LIS5, and HL7 v2.3 define these message structures, as do CEN IN 1613 and 1614. These standards should be examined to ensure their ability to convey the required data values. The logical constellations of data for particular decision support situations, such as emergency medical systems or chronic diseases, and their visual layout, are reported elsewhere.

7.3.3 *Requests and Reports for Logistic Services*—As a result of organizational arrangements that have now become part of the IDS enterprises, the laboratory must also develop resource management information bases that allow it to order and manage the material and human resources used by the laboratory in producing the requested services. Because different contractual arrangements may exist between the laboratory and the nodes serviced and because the supply nodes utilized will employ Electronic Commerce (EC), techniques using Electronic Data Interchange (EDI) will become common. The CLIMS data domain must be organized to produce resource utilization data that is consistent with standard EDI data constellations and that is consistently and automatically converted into an on-time supply delivery schedule adhering to established procurement agreements. The catalog data (see 6.8) must be accessible from the appropriate referential data, developed as described in 7.3.6. Some of the defined EDI messages are shown in Table 10 and further described in LIS8 and in X12 Standards.[14]

7.3.4 *Requests for, and Reports of, Administrative Services*—Most administrative services are related either to R-ADT (see Guide E 1239) or to HIPAA mandated transactions (See X12 standards). The application of these transactions to the clinical laboratory will depend upon the business model and related Enterprise Architecture. These relationships should be spelled out in the IEEE 1362 Concept of Operations document prepared for the System Life Cycle.

7.3.5 *Requests for, and Reports of, Reportable Data*—As the Healthcare Information Domain evolves, the various public and private public health agencies that interact with healthcare enterprises will either request or require certain constellations of data, particularly that which includes clinical services. These data will be exchanged

[14]See the website, http://www.disa.org.

using common syntaxes and will likely be named structures. The information architecture for the enterprise must identify those relating to the enterprise and the way that the available syntaxes can host these constellations.

7.3.6 *Access to Information Services*—One of the new capabilities that will influence clinical laboratory services is the access to context-independent information via telecommunications networks. The attributes of products and services, practice guidelines, knowledge structures of all kinds and other information now produced and distributed as printed catalogs or compilations will be accessible via networking. The value of the content and its use in user interactions will influence whether local or remote networked information sources are developed. The maintenance of content and which attributes of the accessed records are utilized in the business during processing will be important.

8. Description of Alternative Network Implementation Strategies

8.1 The documentation of implementation strategies must rely on three Life Cycle Documents: IEEE 1362 Concept of Operations and, for each component of a defined architecture incorporated within a single project, a Requirements Specification document (IEEE 830 and 1233) and a Project Management Plan (IEEE 1058) document pair for that project. This document triad will prompt the steps in the Life Cycle needed to consider the full range of potential items involved in including new components into an existing architecture in a fashion consistent with the conventions stated in the content Health Informatics standards which enable interoperability consistent with Life Cycle concepts stated in ISO 12207, 15288, IEEE 12207.0, 12207.1, 12207.2. In any Enterprise, the evolution occurs over time. The content conventions and the vocabulary of the practitioner will change over time. For that reason, activities in Section 5, and their inclusion in the Concept of Operations document, are critical to identifying alternative strategies for implementation. The Requirements Specification and the Project Management Plan provide a mechanism for documenting each alternative and noting the conventions (standards from the available list) to be used with that alternative in a fashion consistent with the Life Cycle. As the market perceives system components that incorporate a carefully documented common architectural function, suppliers modularize it such that architects can utilize those functions in producing capabilities in Enterprise Architectures that meet specialty-identified common capabilities. Such modules can then be identified in the Requirements Specification.

9. Selection of an Implementation Strategy and Associated Methods and Techniques

9.1 LIS3, in concert with the documents noted in Section 8, provide a procedure by which procurement of CLIMS can be conducted consistent with best recommended practices. Recent IEEE standards should also be consulted about the acquisition process. In addition, IEEE 1062 Software Acquisition and EIA/IEEE J-Std-016 (Acquirer/Supplier Agreement) provide useful resources to each individual project.

10. Selection of an Evaluation Methodology and Follow-up

10.1 As each component is added to an information architecture supporting clinical laboratory services, it should be evaluated with respect to the Requirement Specification and Project Management Plan Objectives, as well as with respect to the strategic plan and Concept of Operations document. Each evaluation is a learning experience and provides useful information for subsequent projects directed at adding additional components to the Enterprise Architecture. The basis for the evaluation must be identified early on in the Project Management Plan, if the objective data to be used is to be gathered. The IEEE standards identified in Moore **(9)** should be used in selecting the appropriate measurements.

TABLE 1 ISA Framework for Healthcare Informatics Standards

	Why	When	Who	What	How	Where
	Vision [Guidelines]					
Scope (contextual)	Goals (motivation) 1. Personal/Public Health; care delivery business case	Events (time) 2. Identification of significant care/care delivery events	Stakeholders (people) 3. Essential health Service Organizations and Functions	Values (content) 4. Description of important healthcare service and care delivery information	Processes (function) 5. Important healthcare and care delivery services	Locations (network) 6. Identification and description of organization and individual locations
	Design [Standards]					
Enterprise Model (Conceptual)	Objectives 7. Personal health benefit and care delivery business objectives	Timeline 8. Sequence and timelines of healthcare services	Organization 9. Healthcare information workflow	E-R Data Model 10. Semantic description of healthcare processes	Process Model 11. Conceptual activity model of healthcare delivery	Interface Architecture 12. Structure and interrelationship of healthcare facilities
System Model (Logical Design)	Requirements 13. System Functional Requirements	Phases 14. Healthcare event phases and process components	Hierarchies 15. Healthcare information system human-system interface architecture	Logical Data Model 16. Logical data model for healthcare information	Data Flow 17. Application architecture with function and user views	Network Model 18. Connectivity and distributed system architecture
	Implementation [Standards]					
Technology Model (Physical Design)	Knowledge Design 19. System Operational Requirements	Control Structure 20. Healthcare information system control structures	Human-Technology Architecture 21. Healthcare information system human system interface description	Physical Data Model 22. Physical data model for healthcare information	Structure Chart 23. System Design, language specification and structure charts	System Architecture 24. Health system information network detailed architecture
Components (Modules and Subsystems)	Knowledge Definition 25. Technical Requirements	Timing Definition 26. Healthcare Information System component timing descriptions	Security Architecture 27. System Security Architecture and Operations	Data Dictionary 28. Healthcare Information Metadata and DBMS scripts	Program Description 29. Code Statements, Control blocks, DBMS stored procedures	Network Architecture 30. Physical data network components, addresses and communication protocols
	Operation [Standards]					
Functioning System	Strategy 31. Technology Operational Requirements	Schedule 32. Healthcare information system operation Schedules	Organization 33. IS participant description	Data 34. Functioning database, knowledge base	Function 35. User procedural system and documentation	Network 36. Operating health system communication network

TABLE 2 ISA Framework for Clinical Laboratory Informatics Standards

Zachman	Why	When	Who	What	How	Where
	Vision [Guidelines]					
Scope	Goals Provide lab services; Provide integrated decision support	Events 24 Hr Service; Just-in-time inventory; Continuous Resource Mgt; Immediate Claims processing	Stakeholders Clinical Laboratory; Practitioner Clientele; Suppliers; Payors; Patients	Values Services; Requested Data; Supplier Data	Processes Services; Request Data; Specimen accession; Work Mgt; Resource Mgt; Claims processing	Locations Central Lab; Distributed Lab; Practitioner Site of Care Network Domain
	Generic [Standards]					
Enterprise Model	Objectives Request services; Collect/transport Specimens	Timeline Milestone Chart; PERT/CPA/Gantt	Organization IDS; MCO; Reference Lab	E-R Data Model High Level Data Model (IDEFIX)	Process Model Process Model Use Case/Actors (IDEF0)	Interface Architecture Patterns of Service Utilization; Health Benefits/Objectives

Zachman	Why	When	Who	What	How	Where
System Model	Requirements	Phases	Hierarchies	Logical Data Model	Data Flow	Network Model
	Functional requirements; Health Knowledge Architecture	IDEF3 Timeline Diagram	Organizational Hierarchies	CLIMS Data Model; CPR Data Model; IDEFIX/Objects		Information Architecture
	Implementation [Standards]					
Technology Model	Knowledge Design	Control Structure	Human-Technology Architecture Interface Style Guide	Physical Data Model CLIMS/CPR Database Models	Structure Chart	System Architecture
Components	Knowledge Definition Populate Knowledge Databases	Timing Definition	Security Architecture	Data Dictionary CLIMS/CPR Data Dictionaries	Program Description Structure Charts	Network Architecture
	Utilization [Standards]					
Functioning System	Strategy	Schedule	Organization	Data	Function	Network

TABLE 3 Clinical Laboratory General Sizes and Types

Office Practice Laboratory (service types/configurations)
POCT Work Station (service types/configurations)
Large Ambulatory Clinic Laboratory
Hospital/Inpatient-Facility Laboratory
Commercial Reference Laboratory
An external non-clinical LIMS (e.g. environmental)
Master Patient Index
National Provider File

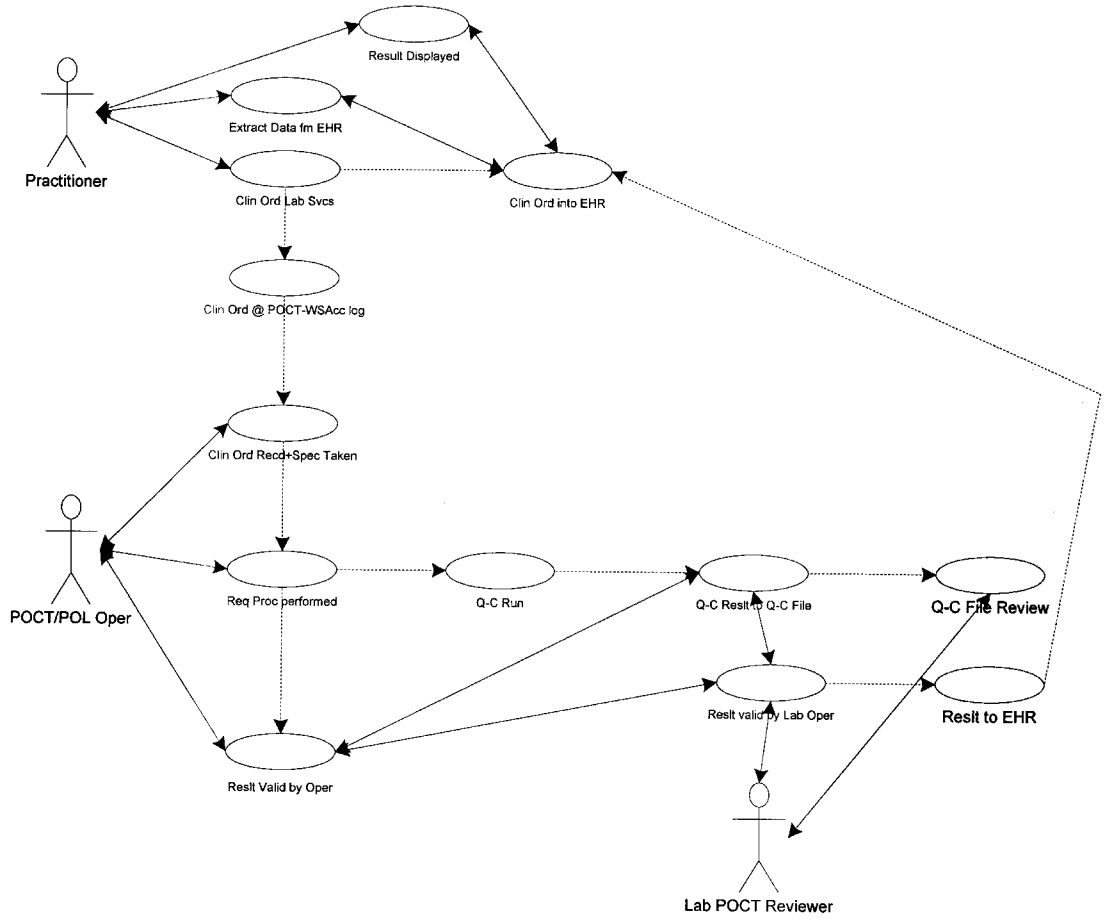


FIG. 1 Use-case Actor Model for a Physician Office Lab (POL) Point-of-Care Testing (POCT) Situation

TABLE 4 Types of Information Domains (Nodes) in a Networked Architecture

Node Type	Relative Numbers
CLIMS	x
Point-of-Care Settings	x
EHR	x
Public Health/Reporting	x
Reference Data	x
Commercial/Administrative	x
Pharmaceutic Services	x
Imaging Services	x

TABLE 5 Non-clinical Information Domains

Trauma Registries
Tumor Registries
Disease (for example, Diabetes) Registries
Immunization Registries
Drug Trial Registries

TABLE 6 Public/Private Reporting Agencies

Centers for Disease Control
State Public Health Laboratories
County/City Public Health Laboratories
National Center for Health Statistics
State Departments of Health
Universities/Research Centers
Private Accrediting Agencies

TABLE 7 Registries

Type	Purpose	Scope
Trauma Registries	Epidemiology	State, Regional, Local
Tumor Registries	Epidemiology	National, Regional, State
Immunization Registries	Public Health	National, State
Occupational Health Registries	Research, Policy	National
Product Safety Registries	Research, Policy	National, Local
Practitioner Profiling	Education, Policy	State, Regional

TABLE 8 Referential Information

Terminologies
Test Directories
Knowledge Representations
Laboratory Commercial Products

TABLE 9 Healthcare Terminologies in the Clinical Laboratory

Procedure Names
Observation/Measurement Names
Rule-based Knowledge Representations
Health Condition/Diagnosis Names

TABLE 10 Common EDI Transaction Sets (x)

ASC X12.84	TS 834 Enrollment Benefit and Maintenance
ASC X12.85	TS 835 Healthcare Claim Payment/Advice
ASC X12.86	TS 837 Healthcare Claim
ASC X12.36	TS 848 Material Safety Data Sheet
ASC X12.374	TS 253 Data Reporting Requirements
ASC X12.281	TS 270 Healthcare Eligibility/Benefit Inquiry
ASC X12.282	TS 271 Healthcare Eligibility/Benefit Information
ASC X12.398	TS 274 Healthcare Provider Information
ASC X12.124	TS 148 Report of Injury or Illness
ASC X12.284	TS 186 Life and Annuity Laboratory Reporting
ASC X12.315	TS 275 Patient Information
ASC X12.316	TS 276 Healthcare Claim Status Request
ASC X12.317	TS 277 Healthcare Claim Status Notification
ASC X12.336	TS 278 Healthcare Claim Review Information
ASC X12.	TS 850 Purchase Order
ASC X12.	TS 855 Purchase Order Acknowledgment
ASC X12.	TS Shipping List
ASC X12.	TS 810 Invoice
ASC X12.	TS Statement
ASC X12.	TS 812 Debit/Credit Adjustment
ASC X12.284	TS 186 Insurance Underwriting Requirements Reporting
ASC X12.	TS 183 Report of Injury or Illness

APPENDIX

(Nonmandatory Information)

X1. EXAMPLES

X1.1

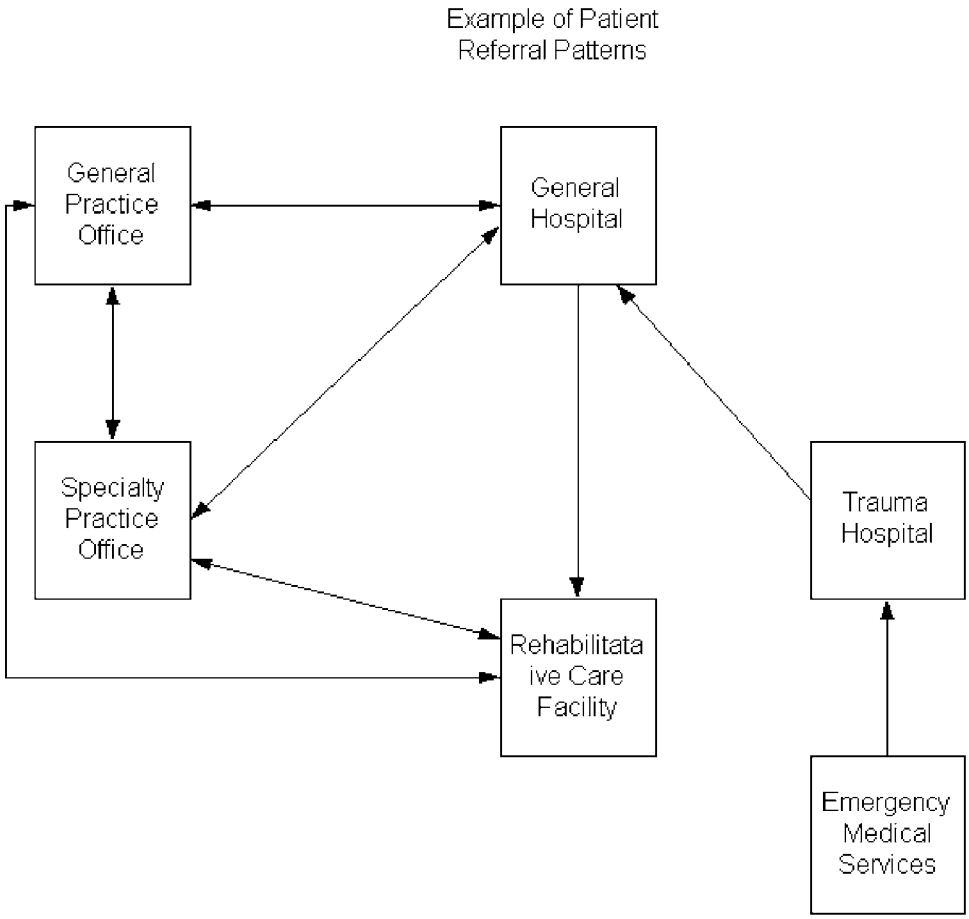


FIG. X1.1 Example of Patient Referral Patterns

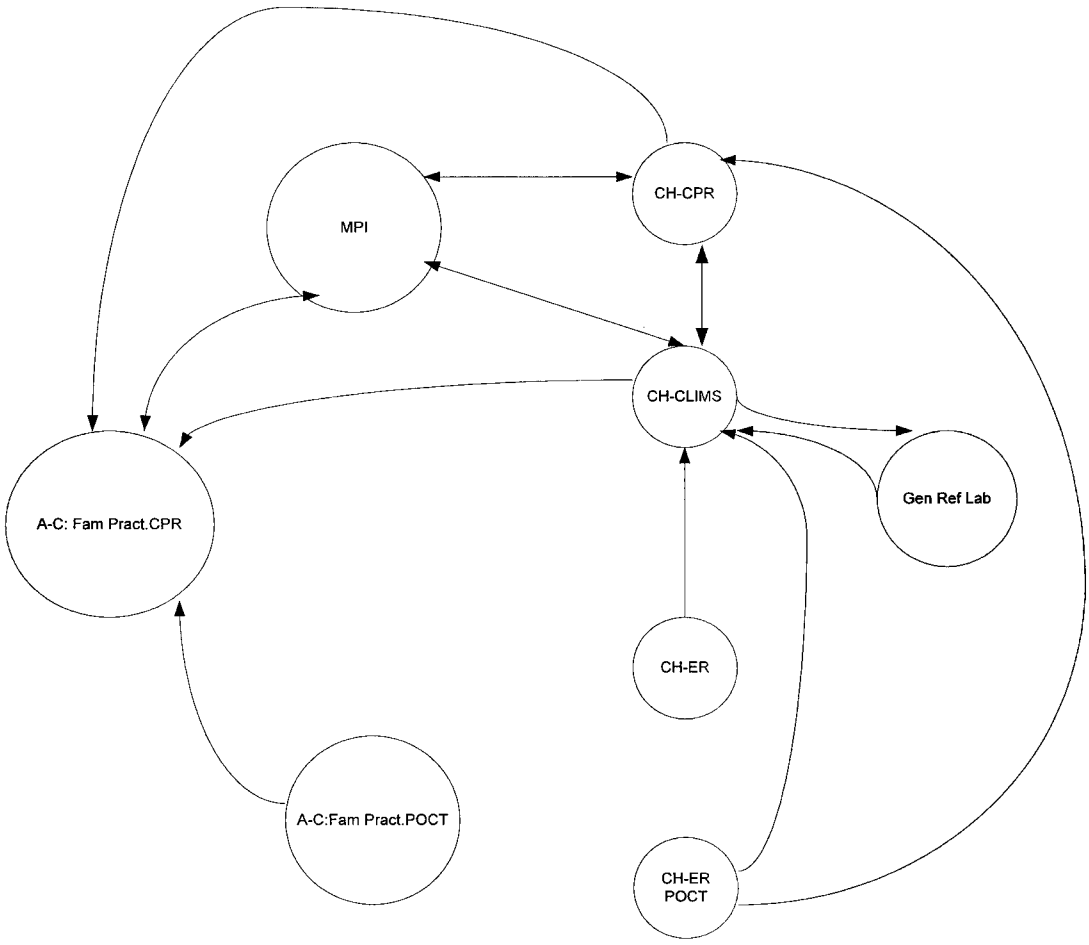


FIG. X1.2 Information Flow Logical Network

REFERENCES

(1) Zachman, J. A., *IBM Systems Journal*, 26/3, 1987.
(2) Harmon, P., Watson, M., *Understanding UML: The Developers Guide with a Web-based Application in Java*.
(3) IDEF Users Group, "The IDEF Framework," 1993.
(4) Jacobsen, I., "Object–oriented Software Engineering: A Use Case Driven Approach," Addison-Wesley, Reading, MA, 1992.
(5) Chen, P., "ACM Transactions in Database Systems Research," 1976.
(6) DeMarco, T., "Structured Analysis and System Specification," Prentice Hall, 1978.
(7) Young, D. C., Nipper, H., Hicks, J., Uddin, D., "Clinician and Chemist: The Relationship of the Laboratory and the Physician," AACC, 1979.
(8) HL7 Framework for Message Development.
(9) Moore, James W., "Software Engineering Standards: a Users Road Map," IEEE, 1998.
(10) Forrey, A.W., McDonald C. J., et al, *Clinical Chemistry*, 42, 1996, pp. 81-90.

NOTES

NOTES

NCCLS ▼ 940 West Valley Road ▼ Suite 1400 ▼ Wayne, PA 19087 ▼ USA ▼ PHONE 610.688.0100
FAX 610.688.0700 ▼ E-MAIL: exoffice@nccls.org ▼ WEBSITE: www.nccls.org ▼ ISBN 1-56238-497-X